REMARKS

Summary of Office Action

In Office Action mailed on February 5, 2008, the Examiner rejected claims 27-30 under 35 U.S.C. 112, second paragraph. The Examiner also rejected claims 16-20 and 31-34 under 35 U.S.C. 112, first paragraph. Finally, the Examiner rejected claims 1-10 under 35 U.S.C. 102(e) over U.S. Patent No. 6,334,446 to Beyar (hereinafter "Beyar"). No other issues were raised.

Summary of Amendment

Upon entry of the present amendment, Claims 1, 16-17, 19, 27, 29, 31 and 33 will have been amended and claim 35 will have been added. Claim 20 is being canceled. Accordingly, Claims 1-10, 16-19 and 27-35 are currently pending in the application. By the present remarks, Applicant submits that the rejections have been overcome and respectfully requests reconsideration of the outstanding Office Action.

Support for the amendment to claim 1 can be found at least in Figures 20, 20A and 21, which show implantable sling portions 806 having anchor mechanisms 808a, 808b formed as a part of, and therefore integral with, the sling portion 806, where the sling portion can comprise an elongate segment of material.

Summary of Interview

Applicant wishes to thank the Examiner for discussing in detail the merits of the case in the telephonic interview conducted on May 21, 2008. The differences between the sling and bone anchors of Beyar, versus the instantly claimed implant with soft tissue anchor mechanisms, were discussed. Also, the recitation of the anchor mechanisms being "integrally formed" upon the ends of the elongate segment of material was proposed and discussed, insofar as such integrally formed anchor mechanisms are believed by Applicant to distinguish from the non-integral and separately provided bone anchor and sling as taught by Beyar. Applicant remains very grateful to the Examiner for all of his assistance and advice.

The Examiner also requested that Applicant review the recently issued parent case corresponding to Application Serial no. 09/733,455, now U.S. Patent No. 7,326,213, for any potential obviousness-type double patenting issues. Applicant respectfully notes that a terminal disclaimer regarding to this parent application was filed in the instant case on October 1, 2007, and thus any obviousness-type double patenting issue over this patent is believed to be obviated.

Applicant's Response

1. Rejection of Claims 27-30 under 35 U.S.C. 112, Second Paragraph

The Examiner rejected claims 27-30 under 35 U.S.C. 112, second paragraph, as being indefinite because the method of claim 27 depended from claim 1, which claim is drawn to an implant, not a method (*see, e.g.,* Office Action page 2).

Claim 27 is being amended herewith to properly depend from method claim 16, and thus claim 27 and claims 28-30 depending therefrom are now believed to be in proper form. Accordingly, withdrawal of the rejection of the claims 27-30 is respectfully requested.

2. Rejection of Claims 16-20 and 31-34 under 35 U.S.C. 112, First Paragraph

The Examiner rejected claims 16-20 and 31-34 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement because the Examiner asserts that the specification does not have adequate support for the recitation of a deployment mechanism that is a "non-mechanically assisted" mechanism as in claim 16 (*see, e.g.,* Office Action page 2.) This rejection is respectfully traversed.

Claim 16 is being amended herewith to recite, *inter alia*, "providing a ~~non-mechanically assisted~~ deployment mechanism for positioning said anchor mechanisms of said implantable sling within said target site of said soft tissue." In other words, claim

16 is being amended to delete any reference to the deployment mechanism being "non-mechanically assisted," and thus this claim and the claims depending therefrom are considered to meet the requirements of 35 U.S.C. 112, first paragraph. Accordingly, the rejection of claims 16-20 and 31-34 is respectfully requested to be withdrawn.

Furthermore, although the Beyar reference applied to claims 1-10 of the instant application has not been applied in the most recent Office Action in rejecting claim 16, Applicant wishes to point out for the record that Beyar does not teach or suggest the method of claim 16. In particular, claim 16 is drawn to a method of surgically implanting a sling by advancing one of the anchor mechanisms toward a soft tissue site via a deployment mechanism and "selectively detaching said anchor mechanism from said deployment member such that *said anchor mechanism becomes embedded within a first mass of soft tissue*" (emphasis added, step d) of claim 16), and advancing the other mechanism toward a soft tissue site and "detaching said respective other anchor mechanism from said deployment member and *embedding said anchor mechanism within a second mass of soft tissue*" (emphasis added, step f) of claim 16.)

In other words, claim 16 is drawn to a method in which anchor mechanisms are embedded within *soft tissue*, such as for example a membrane tissue and/or fascia, to anchor the mechanisms within the soft tissue. The instantly claimed method in which anchor mechanisms are embedded within soft tissue to surgically implant slings represents a significant and non-obvious advance over prior methods, such as methods involving the implantation of anchors into bone, because it allows for more control and versatility in terms of placement and/or replacement of the anchors and/or sling within the patient, and is also typically a substantially less invasive procedure as it does not require either the *drilling* or *propulsion implantation* of materials into the hard bone tissue.

In contrast, as understood by Applicant, Beyar is drawn exclusively to methods and techniques for the insertion of anchors into hard *bone* for the surgical insertion of slings. For example, Beyar teaches the use of "bone anchors, whether of screw or staple type" (Abstract) and also teaches that a stapler can be used to "provide the forcible ejecting, pushing, and implanting of the bone anchor or staple 835 with attached suture thread, into bone" (column 10, lines 62-66.) Thus, Beyar is concerned with *bone anchors* and methods of implantation thereof with devices that provide adequate propulsion to embed the anchors within the *bone*. Beyar does not teach or suggest implanting anchors within *soft tissue*, and also does not recognize any benefits of doing so, and as such Beyar does not teach or suggest each and every limitation of claim 16.

Accordingly, it is considered that not only does claim 16 meet the requirements of 35 U.S.C. 112, first paragraph, as discussed above, but also claim 16 is patentable over the references of record. Accordingly claim 16 and the claims depending therefrom, including claims 17-20 and 27-35, are considered to be in allowable form. Early notice as to the allowability of claims 16-20 and 27-35 is therefore respectfully requested.

3. Rejection of Claims 1-10 under 35 U.S.C. 102(e) as being Anticipated by Beyar

The Examiner rejected claims 1-10 under 35 U.S.C. 102(e) as being anticipated by Beyar. The Examiner asserts that Beyar teaches the claimed implant with anchor mechanisms and a sling and/or elongate segment of material (*see, e.g.*, Office Action page 3.) The Examiner further argues that "while the intended use of Beyar may not be securing the anchor mechanism within the soft tissue the Beyar device is clearly capable of being secured at such a location within the body" (Office Action page 4). This rejection is respectfully traversed.

Claim 1 is being amended herewith to recite:

> "An implant for providing support to an anatomical structure comprising:

> a) an elongate segment of material having first and second opposed ends, said segment of material being operatively positionable adjacent said anatomical structure to be supported; and
>
> b) at least one anchor mechanism integrally formed upon a respective one of said ends of said segment of material, said anchor mechanism being operatively configured to be advanceable into a soft tissue mass at a target site in a first direction and resistant to movement in an opposite direction in the soft tissue, the anchor mechanism being configured to become permanently fixed in position within the soft tissue" (underline added).

In other words, claim 1 has been amended to require that the anchor mechanism be formed *integrally* upon an end of the elongate segment of material, which integral configuration is not taught or suggested by Beyar.

Instead, Beyar teaches insertion of a medical sling using bone anchors that are provided separately and non-integrally with the sling material (*see, e.g.,* Abstract). In particular, Beyar teaches a bone anchor comprising a staple that is forcefully ejected from a stapler device to penetrate and implant the staple into bone (*see, e.g.,* column 9, line 65 through column 10, line 10.) A suture thread 20 is attached to the staple, such as by threading the suture thread through an opening formed in the body of the staple (*see, e.g.,* column 9, lines 25-31), as is shown for example in Figures 2-3 and 13-19. A separate sling can then be introduced, such as by threading along the sutures, and the sutures are tied to allow fine tuning of the sling tension (*see, e.g.,* column 17, line 65 through column 18, line 5). Thus, Beyar teaches a system *consisting of three separate and individual parts*, namely bone anchor(s), suture(s), and a sling, *which are not integral with one another*, but rather are separate pieces attached to one another by threading or tying of the sutures. Accordingly, the medical sling and system of Beyar does not anticipate the integrally formed implant of claim 1.

Furthermore, it is noted that the implant of the instant invention provides substantial advantages over the medical sling systems using sutures such as those taught by Beyar. In particular, a problem that arises with bone anchor/suture systems such as those taught by Beyar is that the sling tension typically must be adjusted by the tightening/loosening of the suture line, which can result in breaking of the suture lines and thus failure of the sling. In contrast, Applicant has discovered an improved implant configuration that allows for the insertion and embedding of the anchor mechanisms in soft tissue, as opposed to bone as in Beyar, and thereby allows for more precise tension adjustments merely by adjustment of the depth of insertion of the anchor mechanisms. That is, the desired tension of the implant can be provided by selecting the depth of insertion of the anchor mechanisms into the soft tissue. The soft tissue anchor mechanisms of the instant invention are therefore advantageously formed *integrally* on the ends of the elongate segment of material of the implant, thereby eliminating the need for connecting sutures and the reducing the likelihood of breakage or failure of the implant, while still allowing for the desired tension adjustment.

Accordingly, it is considered that claim 1 and the claims depending therefrom are not anticipated by Beyar, and the rejection of these claims over Beyar is respectfully requested to be withdrawn.

It is furthermore noted that claim 1 is not anticipated by Beyar because Beyar does not teach anchor mechanisms that are configured to become fixed in position within soft tissue, as recited in the claim. Instead, as discussed above, Beyar it directed to the use of *bone anchors* and techniques for implanting the bone anchors within *bone*, which is not a soft tissue as understood by those of ordinary skill in the art. For example, Beyar teaches the use of "bone anchors, whether of screw or staple type" (Abstract) and also teaches that a stapler can be used to "provide the forcible ejecting, pushing, and implanting of the bone anchor or staple 835 with attached suture thread, into bone" (column 10, lines 62-66.) Thus, while Beyar is concerned with *bone anchors* and methods of implantation thereof with devices that provide adequate propulsion to embed within *bone*, Beyar does not teach or suggest anchors that are implantable within ***soft tissue***, and also does not recognize any benefits of implanting or fixing anchors within soft tissue. Thus Beyar does not teach or suggest the claimed implant having the soft tissue anchors are recited in claim 1.

Furthermore, contrary to the Examiner's assertion, the bone anchors as taught by Beyar are not understood to be suitable or desirable for implantation or fixing within soft tissue, as with the anchor mechanisms of the instant claims. The bone anchors of Beyar are capable of being inserted via propulsion into bone material (*see, e.g.,* column 10, lines 62-66), and thus can be understood to be configured to be injected or otherwise forcefully inserted into bone, such as by being made of a relatively hard and even heavy material, and being shaped to be capable of readily penetrating bone. For Example, Beyar teaches the bone anchors being made of hard metal materials such as Nitinol or stainless steel alloy, and having dramatically sharpened tips that allow the anchors to pierce bone (*see, e.g.,* column 12, lines 54-55, column 14, lines 19-30 and Figures 2-3 and 13-19)

In contrast, the soft tissue anchors of the instantly claimed invention are configured to become embedded or fixed within soft tissue and thus comprise characteristics that render them suitable for fixation within said soft tissue. As understood by those of ordinary skill in the art, a primary difference between soft tissue and bone is that soft tissue can be susceptible to excessive rupture and tearing when objects are implanted and/or moved through the tissue. Thus, the soft tissue anchors of the instant invention are configured such that they can be advanced through the soft tissue and resist movement in a direction opposite such advancement, as claimed, without excessively tearing or otherwise stressing the soft tissue. In contrast, the possible rupture of soft tissue is not of concern in the use of the bone anchors of Beyar, and indeed the bone anchors are preferably constructed to optimize the piercing of hard tissue without concern for whether the anchors might rip or damage soft tissue. In other words, the successful implantation of anchors into bone requires different and even contradictory requirements than the implantation of anchors into soft tissue. Accordingly, despite the Examiner's assertion to the contrary, it is considered that one of ordinary skill in the art would not consider the bone anchors of Beyar to be capable of fixing or implantation within soft tissue, as in the claimed implant.

A closer examination of the anchors taught by Beyar further confirms the non-interchangeability of the bone anchors taught therein versus the claimed soft tissue anchors. For example, each of Figures 3, 13-16 and 18 of Beyar depicts a virtually straight-edged anchor with a sharpened tip. Beyar explains that the straight anchors, such as in Figure 3 (held straight by an insertion device), deform after injection into bone into "curved" forms, as depicted in Figure 2, as a result of shape memory of the material being used, and thereby better secure the anchors into the bone (*see, e.g.,* column 9, lines 33-43.) However, by viewing the "curved" form of Figure 3 and further as depicted in Figures 8A-8E, it can be readily seen that while such a "curved" form may be suitable for penetrating into and then deforming to secure within hard bone, the curved form would likely merely slip out of place if inserted into soft tissue, as the anchor is not otherwise configured to resist a pull out of soft tissue. Thus, one of ordinary skill in the art would recognize that such deformable anchors would not be suitable for use in soft tissue.

The Examiner further specifically refers to Figure 17 as showing an anchor with barbs (515) "that would resist movement in an opposite direction" (Office Action page 3.) However, as discussed above, the type of shape and configuration that renders an anchor suitable for embedding or fixing within one type of either soft or hard tissue does not necessarily render it suitable for, or capable of, embedding in the other type of tissue, because the requirements for soft versus hard tissue are different and even contradictory to one another. Thus, for example, while the anchor of Figure 17 shows small barbs 515, there is no reason to believe that such barbs would be capable of embedding and/or fixing the anchor within soft tissue. For example, there is no evidence that the barbs 515 are angled at a degree or have a length of width that would hold the anchor in the soft tissue, rather than merely ripping through the soft tissue. There is also no evidence that the sharpened tips of the barbs would not excessively slice through the soft tissue upon exertion of any opposing motion. Indeed, as hard tissue is substantially less susceptible to ripping or shredding than soft tissue, and as the barbs provided for insertion in bone are desirably angled and sharpened to provide the maximum degree of stability within the bone, it is highly likely that the sharpened barbs of the anchor of Figure 17 would in fact excessively rip or shred soft tissue if it were attempted to implant the bone anchors in said soft tissue. Thus, it is considered that one of ordinary skill in the art would consider the bone anchor mechanisms of Beyar to be *not capable* of being embedded and/or fixed into *soft tissue* for the purposes of implanting a sling, i.e. without excessive ripping and shredding of the soft tissue, and/or without slippage of the mechanism in the soft tissue, resulting in an unacceptably high failure rate, and thus the bone anchors of Beyar are not considered to meet the limitations of the soft tissue anchors as claimed. Moreover, as Beyar does not teach or suggest the desirability of embedding and/or fixing anchors into soft tissue, and instead is directed almost entirely to techniques and methods for injecting into Bone, it is considered that the instantly claimed implant having the soft tissue anchor mechanisms are also not obvious over the teachings of Beyar.

The difference between anchor mechanisms capable of implantation in soft tissue versus those implantable in hard bone tissue may be further illustrated by way of analogy to hardware anchors used in construction and building materials. As can be experienced by any person visiting a hardware store, hardware anchors differ in size, shape and configuration according to the particular anchoring application for which they are intended as well as according to the particular substrate (drywall, concrete, brick, wood, etc.) that they are being used to anchor to. It can further be seen that the type of anchor suitable for fixing something to an ordinary household wall (such as a nail or drywall anchor) is not the same or interchangeable with anchors for anchoring materials to concrete. Instead, the different anchors are particularly and separately configured for insertion into the different materials, as well as retention within the individual materials. Similarly, it can be understood that anchor mechanisms for embedding into soft tissue versus hard bone tissue would necessarily differ in terms of their size, shape and configuration to provide retention within the different materials, and thus could not be considered to be interchangeable with one another.

Accordingly, it is considered that the bone anchors of Beyar do not anticipate the implant having the soft tissue anchors of claim 1, and claim 1 and the claims depending therefrom are patentable over this reference. The rejection of claim 1 and the claims depending therefrom is thus respectfully requested to be withdrawn.

Conclusion

Applicant respectfully submits that each and every pending claim of the present invention meets the requirements for patentability under 35 U.S.C. §§ 112 and 102(e), and respectfully requests that the Examiner indicate allowance of each and every pending claim of the present invention. In view of the foregoing, it is submitted that none of the references of record anticipate or render obvious Applicant's invention as recited in each of Claims 1-10, 16-19 and 27-35.

Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested.

If any additional fee is required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

Date: 5/23/08 By:

Customer No.: 007663

Matthew A. Newboles
Registration No. 36,224
STETINA BRUNDA GARRED & BRUCKER
75 Enterprise, Suite 250
Aliso Viejo, California 92656
Telephone: (949) 855-1246
Fax: (949) 855-6371

MAN/AMC
T:\Client Documents\BENDF\004B2\ROA.02052008.doc